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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,978	06/25/2003	John Keeney Howie	9287	3736

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THE PROCTER & GAMBLE COMPANY
INTELLECTUAL PROPERTY DIVISION
WINTON HILL TECHNICAL CENTER - BOX 161
6110 CENTER HILL AVENUE
CINCINNATI, OH 45224

[REDACTED] EXAMINER

HENDRICKS, KEITH D

ART UNIT	PAPER NUMBER
1761	

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/603,978	HOWIE ET AL.	
	Examiner	Art Unit	
	Keith Hendricks	1761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-18 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 25 June 2003 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/12/04</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "reduced", regarding the end product of a method, as well as found in product claims 13 and 15, is a relative term which renders the claim indefinite. The term "reduced" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The term "reduced" indicates both a current condition and a previous condition, as well as a change from the previous to the current state. A product, as it stands in its current state, cannot simply be "reduced", without reference to a standard or to the previous condition. Further, as an example, if two distinct food products each contain 350 ppb of acrylamide, where one naturally contained said amount and one had been processed according to the invention, given this data alone, it would be impossible for one skilled in the art to determine which one had been "reduced" from a previously higher amount, and which one was naturally at this level. This also applies to amounts of reducing sugars. Still further, it is noted that a food product cannot have a "reduced amount of acrylamide", if it never had a previous level of acrylamide, as is the case with food products which have not yet been heated to form acrylamide.

The term "low" in (at least) claims 14 and 16, is a relative term which renders the claims indefinite. The term "low" is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. There is no standard or original amount of acrylamide provided in the specification such that one skilled in the art (or a consumer of the claimed article) would be apprised of what constituted a "low" amount of acrylamide within the article.

Claim 18 is indefinite, as it refers to the "article of claim 18, wherein said food product is a food ingredient." This does not further limit the invention of claim 17, as claim 17 already provides for "a food ingredient."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Gerrish et al. (US PAT 5,620,727).

Gerrish et al. disclose a method for producing a fried potato food. At columns 6-7, in the Control and Example 4, fresh potatoes are sliced, and then “washed in a large volume of cold water to remove surface starch and sugars.”

Thus the reference anticipates the invention. Potatoes are well-known to contain large amounts of reducing sugars. The instant claims simply require the reduction of the level of said sugars in the food material.

Claims 1-3, 5-6 and 8-12 are rejected under 35 U.S.C. 102(a) as being anticipated by Soeda et al. (US PAT 6,383,533).

Soeda et al. disclose the production of enzyme-treated protein-containing foods, where a food containing protein is treated with a transglutaminase and an oxidoreductase. At column 8, it is stated that glucose oxidase is the preferred oxidoreductase. Various treatment procedures, including times and the amounts of the enzyme to be added to the foodstuff are disclosed, and the foodstuff is eventually heated. Various foodstuffs are disclosed for use in the method, including pastas, noodles, egg whites, fish-pastes, meat products, etc.

Thus the reference anticipates the invention. While the reference does not disclose the amount of “reduction” of acrylamide in the final food product, the referenced method steps are identical to those instantly claimed and disclosed, and thus the results would be expected to be the same, as an inherent result of the natural function of the enzyme and method disclosed, absent any clear and convincing evidence and/or arguments to the contrary. Regardless, as noted in the 35 U.S.C. 112, second paragraph rejection above, there is no set means by which one skilled in the art may determine how much acrylamide has been “reduced” from a final product, when there was no original amount of acrylamide in the final product.

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Claims 1-3, 5-6 and 8-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Sato et al. (EP 0 468 731).

Sato et al. disclose the addition of a bread improver to a dough, for producing baked bread products. The improver comprises glucose oxidase. Various treatment procedures, including times and the amounts of the enzyme to be added to the dough are disclosed, and the dough is eventually baked to form a finished product.

Thus the reference anticipates the invention. While the reference does not disclose the amount of "reduction" of acrylamide in the final bread product, the referenced method steps are identical to those instantly claimed and disclosed, and thus the results would be expected to be the same, as an inherent result of the natural function of the enzyme and method disclosed, absent any clear and convincing evidence and/or arguments to the contrary. Regardless, as noted in the 35 U.S.C. 112, second paragraph rejection above, there is no set means by which one skilled in the art may determine how much acrylamide has been "reduced" from a final product, when there was no original amount of acrylamide in the final product.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of the following: Soeda et al. or Sato et al.

Both Soeda et al. and Sato et al. are taken as cited above.

Regarding claims 13-18, it would have been obvious to one of ordinary skill in the art to have packaged and appropriately labeled the food products produced by the references. Packaging and labeling techniques were well-known and common in the art, especially regarding any potential special feature that might draw the interest of the consumer. Regarding the particular message, it is noted that the

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printed word itself would not significantly change the claimed article of matter, and would not provide a patentable distinction, *per se*, over the known prior art package materials and methods. Note that claims 15-18 do not even refer to, nor require, a heated or cooked product, and thus do not necessitate a “reduced amount of acrylamide” formation.

Double Patenting – Non-statutory

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

i) Claims 13-14 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of copending Application No. 10/606,260. Although the conflicting claims are not identical, they are not patentably distinct from each other because they each are directed to food products with reduced amounts of acrylamide; methods of making said products; and/or articles of commerce comprising said products. The article claims in each application comprise (a) a snack chips food product with a reduced level of acrylamide; (b) a container for containing the product, and (c) a message associated with the container, wherein said message associated with the container informs the consumer that the product has a “reduced level of acrylamide.”

ii) Claims 13-14 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-44 of copending Application No. 10/603,279. Although the conflicting claims are not identical, they are not patentably distinct from each other because they each are directed to food products with reduced amounts of acrylamide; methods of making said

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products; and/or articles of commerce comprising said products. The article claims in each application comprise (a) a snack chips food product with a reduced level of acrylamide; (b) a container for containing the product, and (c) a message associated with the container, wherein said message associated with the container informs the consumer that the product has a “reduced level of acrylamide.”

iii) Claims 1-12 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11-44 and 47-50 of copending Application No. 10/606,137. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are directed to food materials and articles of commerce with “reduced level of acrylamide”, as produced by any method, and the copending claims are directed to methods of producing food materials with reduced levels of acrylamide, as well as articles of commerce containing such (as explained above with regard to copending application 10/606,260).

iv) Claims 13-14 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-57 of copending Application No. 10/603,973. Although the conflicting claims are not identical, they are not patentably distinct from each other because they each are directed to food products with reduced amounts of acrylamide; methods of making said products; and/or articles of commerce comprising said products. The article claims in each application comprise (a) a snack chips food product with a reduced level of acrylamide; (b) a container for containing the product, and (c) a message associated with the container, wherein said message associated with the container informs the consumer that the product has a “reduced level of acrylamide.”

v) Claims 13-14 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of copending Application No. 10/603,278. Although the conflicting claims are not identical, they are not patentably distinct from each other because they each are directed to food products with reduced amounts of asparagine and/or acrylamide; methods of making said products; and/or articles of commerce comprising said products. The article claims in each application comprise (a) a snack chips food product with a reduced level of acrylamide; (b) a container for containing the product, and (c) a message associated with the container, wherein said message associated with the container informs the consumer that the product has a “reduced level of acrylamide.”

Double Patenting -- Statutory

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

- i) Claims 13-14 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 45-46 of copending Application No. 10/606,137. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

- ii) Claims 13-14 are directed to the same invention as that of claims 45-46 of (presumably) commonly assigned 10/606,137. The issue of priority under 35 U.S.C. 102(g) and possibly 35 U.S.C. 102(f) of this single invention must be resolved.

Since the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302), the assignee is required to state which entity is the prior inventor of the conflicting subject matter. A terminal disclaimer has no effect in this situation since the basis for refusing more than one patent is priority of invention under 35 U.S.C. 102(f) or (g) and not an extension of monopoly.

** It is requested that such statements are made in the '137 application, as well.

Failure to comply with this requirement will result in a holding of abandonment of this application.

Allowable Subject Matter

The following is a statement of reasons for the indication of allowable subject matter:

Claims 4 and 7 are free of the prior art of record. Aldose reductase is also known as an aldehyde reductase. As stated in US Patent 5,738,878, "aldose reductase is an enzyme (designated EC 1.1.1.21) which catalyzes the conversion of glucose to sorbitol and which is involved in the pathogenesis of certain diabetic complications. In particular, the excess production of sorbitol has been linked with cataracts, retinopathy, keratopathy, neuropathy, myopathy, and nephropathy, and the like." "Mounting experimental evidence indicates that the NADPH-dependent reduction of glucose to the sugar alcohol sorbitol, catalyzed by aldose reductase, provides a common link in the onset of long-term diabetic complications that result in tissue and/or functional changes in the cornea, lens, retina, iris, peripheral nerves and kidney." As these adverse reactions were known to occur within the body, there has been no teaching or motivation in the art to utilize the aldose reductase enzyme in foodstuffs, in order to reduce or eliminate levels of reducing sugars in food materials in order to prevent the formation of acrylamide upon heating.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith Hendricks whose telephone number is (571) 272-1401. The examiner can normally be reached on M-F (8:30am-6pm); First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on (571) 272-1398. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



KEITH HENDRICKS
PRIMARY EXAMINER